

## **REMARKS**

### **I. THE SPECIFICATION**

Applicants amend the specification herein to reference the priority applications.

### **II. THE REJECTION UNDER 35 U.S.C. § 112**

The Office Action rejects claims 6 and 7 under 35 U.S.C. § 112, first paragraph. In particular, the Office Action requires a showing that the biological materials disclosed in the specification, namely hybridoma cells J&JPRD/hAb11/1 and J&JPRD/hAb11/2, would be made available to the public.

In response, Applicants submit that the invention claimed in claims 6 and 7 have been deposited with the Belgian Coordinated Collections of Microorganisms (BCCM) an International Depositary Authority (IDA) established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and recognized by the U.S. Patent Office. See MPEP 2405; 37 CFR § 1.803. Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122, and all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent. 37 C.F.R. § 1.808.

The specification is amended herein to more properly reference the deposited biological material.

Reconsideration and withdrawal of the rejection of claims 6 and 7 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

### **III. THE REJECTION UNDER 35 U.S.C. § 102**

The Office Action rejects claims 1-5, 8-11 and 13-16 as being anticipated by Walker et al., J. Neuropathol. Exp. Neurol., 377-383 (1994); WO0162801; and Naslund et al. Applicants respectfully traverse the rejection.

Walker et al. reference discloses a monoclonal antibody for the NH<sub>2</sub>-terminal end of the Abeta peptides departing from the immunogen consisting of the first 1-16 AA of Abeta. The antibodies of the present invention differ in that they are specific for the truncated form of Abeta, i.e., obtained upon cleavage of position 11 of the Abeta, generating shorter Ab11-40 and Ab11-42 peptides. The antibodies of the present invention have no cross reactivity with other APP fragments and are accordingly useful in an immunoassay to assess the role of Ab11-x peptides in the pathogenesis of Alzheimer's disease. Simply based on the abstract the Mab described in Walker et al., only allows one to determine total Abeta in the brains of living

nonhuman primates and would not differentiate between the full length and truncated forms of Abeta.

Similarly, Pirttila et al. and WO0162801 provide Mab's that are specific for Abeta 13-28, i.e., would not detect the NH2-terminus of the Abeta 11-x peptides and are therefore accordingly non-specific for these truncated forms. Pirttila et al. and Naslund et al. provide a Mab (the Mab 6E10 is the same for both references) specific for Abeta 1-16, again this antibody does not allow one to differentiate between the different Abeta peptides as shown in the Immunoblotting result on page 8380 of the Naslund et al. reference. Total Abeta is detected as a single band and differentiation of the different Abeta forms, including the identification of the Abeta 11-40 peptide was only realized using MS-analysis of the purified Abeta peptides. In other words, none of the Mab's provided in the cited references have the specificity of the Mab's of the present application, a specificity which is demonstrated in the Sandwich ELISA on page 23 and corresponding figures 2A-C of the present specification.

Reconsideration and withdrawal of the rejection of claims 1-5, 8-11 and 13-16 under 35 U.S.C. § 102 are respectfully requested.

#### IV. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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Attachment:  
- Deposit Information